



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
FAX: (513) 679-2771

April 8, 2004

**WARNING LETTER**  
**CIN-04-201679**

**via Federal Express**

Ralph K. Halter, President  
Halter Feed & Grain, Inc.  
11501 Baywood Street  
Robertsville, OH 44670

Dear Mr. Halter:

An inspection of your unlicensed feed mill, Halter Feed & Grain, Inc., located at 405 Tremont Ave. SW, Massillon, OH 44646, conducted by Food and Drug Administration investigators, on 11/21-12/03/2003, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 (21 CFR 589.2000) – Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) and misbranded within the meaning of Section 403(f) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigator found the following violations of 21 CFR 589.2000:

- 1) failure to label products that contain or may contain prohibited materials with the caution statement – “**Do not feed to cattle or other ruminants**”, as required by 21 CFR 589.2000(d)(1);
- 2) failure to establish and maintain written procedures, including clean-out and flushing procedures, to avoid commingling and cross-contamination of common equipment, as required by 21 CFR 589.2000(e)(1)(iv);
- 3) failure to maintain records sufficient to track prohibited materials throughout their distribution in that you do not always document the customer name or address for the sale and distribution of feeds containing meat and bone meal, as required by 21 CFR 589.2000(d)(1).

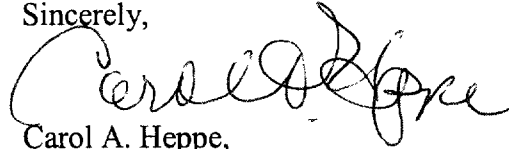
The above is not intended as an all-inclusive list of CGMP violations. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should notify this office, in writing, within fifteen (15) working days of the receipt of this letter of the present operational status of this facility. We understand that this facility may have

been put out of production by a fire that occurred on January 16, 2004. Since there is the possibility that the facility will again be operational, you should include an explanation of each step that will be taken to correct the violations and prevent their recurrence.

Your response should be directed to Charles S. Price Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237-3097. If you have any questions regarding this letter, you may call Mr. Price at telephone (513) 679-2700 extension 165.

Sincerely,

A handwritten signature in black ink, appearing to read "Carol A. Heppe". The signature is fluid and cursive, with a large initial "C" and "H".

Carol A. Heppe,  
District Director  
Cincinnati District

Cc: George H. Snyder, Manager  
Halter Feed & Grain, Inc.  
P.O. Box 821  
Massillon, OH 44648